

## ENZYMATIC THERADY

INCORPORATED

What Better feels like."

### INTEGRATIVE THERAPEUTICS INC."

NF Formulas + PhytoPharmica Tyler Encapsulations + Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 + F: 503.582.0467

### **ENZYMATIC THERAPY** PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.9099 F: 920.469.4418 (Phyto)

October 19, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

Beta Glucan Complex	Beta Glucan Complex combines oat beta-glucan, chromium, biotin, and potent antioxidants in a convenient, powdered drink mix.*	Vitamin C (as ascorbic acid), Biotin, Chromium (from chromium picolinate), Beta Glucan (from Soluble Oat Fiber), HIActives Berry Blend-Wild Blueberry fruit, Marion Blackberry fruit, & Bilberry fruit, AnthoRedoxon™ (10% Anthocyanins), Beet Root extract (Beta vulgaris), Bilberry Fruit extract (Vaccinium myrtillus), Black Current Fruit extract (Ribes nigrum), European Elder Fruit extract (Sambucus nigra), Stevia Leaf Extract (Stevia rebaudiana)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading. 1 0000

By:	FLECHE			
Title:	Robert Doster Senior Vice President of Scientific Affairs			
Date:	10/19/04			

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If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux Chief Financial Officer



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# ENZYMATIC THERAPY & PHYTOPHARMICA\*

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 • F: 888.570.6460 (Enzymatic) P: 920.469.9099 • F: 920.469.4418 (Phyto)

October 19, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

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MANORUM NENEE		
Beta Glucan Complex	Oat beta-glucan is well described in scientific literature for its efficacy.* It has been shown to support glucose metabolism and endothelial function.*	Beta Glucan (from Soluble Oat Fiber)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KLICILL

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/19/04

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Sincerely,

Michael P. Devereux Chief Financial Officer



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October 20, 2004

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Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

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Beta Glucan	Antioxidants, including vitamin C, have been shown to	Vitamin C (as ascorbic acid)
Complex	support endothelial function and glucose homeostasis.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: #LICUL

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/20/04

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Sincerely,

Chief Financial Officer